AMENDMENT TO THE CLAIMS

The listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (Currently amended) Ondansetron hydrochloride dihydrate having a purity of at least about 99.0% and an exo-methylene content of less than ~~about~~ 0.01%.

2. (Currently amended) Ondansetron hydrochloride dihydrate having a purity of at least about 99.5% and an exo-methylene content of less than ~~about~~ 0.01%.

3. (Currently amended) Ondansetron hydrochloride dihydrate having a purity of at least about 99.9% and an exo-methylene content of less than ~~about~~ 0.01%.

Claims 4-41 (canceled)

42. (Currently amended) Ondansetron hydrochloride dihydrate having a purity of at least about 99.0% and an exo-methylene content of less than ~~about~~ 0.01% prepared by the process of:

a) preparing a solution of ondansetron base in water;

b) acidifying the solution with hydrogen chloride to form a precipitate;

c) washing the precipitate; and

d) crystallizing pure ondansetron hydrochloride dihydrate from water and in the presence of activated carbon.

43. (Currently amended) Ondansetron hydrochloride dihydrate having a purity of at least about 99.5% and an exo-methylene content of less than ~~about~~ 0.01% prepared by the process of:

a) preparing a solution of ondansetron base in water;

b) acidifying the solution with hydrogen chloride to form a precipitate;

c) washing the precipitate; and

d) crystallizing pure ondansetron hydrochloride dihydrate from water and in the presence of activated carbon.

44. (Currently amended) Ondansetron hydrochloride dihydrate having a purity of at least about 99.9% and an exo-methylene content of less than ~~about~~ 0.01% prepared by the process of:

a) preparing a solution of ondansetron base in water;

b) acidifying the solution with hydrogen chloride to form a precipitate;

c) washing the precipitate; and

d) crystallizing pure ondansetron hydrochloride dihydrate from water and in the presence of activated carbon.

45. (Currently amended) A pharmaceutical formulation comprising ondansetron hydrochloride dihydrate, wherein the ondansetron hydrochloride dihydrate has a purity of at least about 99.0% and an exo-methylene content of less than ~~about~~ 0.01%, and wherein the ondansetron hydrochloride dihydrate is prepared by the process of:

a) preparing a solution of ondansetron base in water;

b) acidifying the solution with hydrogen chloride to form a precipitate;

c) washing the precipitate; and

d) crystallizing pure ondansetron hydrochloride dihydrate from water and in the presence of activated carbon.

46. (Currently amended) A pharmaceutical formulation comprising ondansetron hydrochloride dihydrate, wherein the ondansetron hydrochloride dihydrate has a purity of at least about 99.5% and an exo-methylene content of less than ~~about~~ 0.01%, and wherein the ondansetron hydrochloride dihydrate is prepared by the process of:

a) preparing a solution of ondansetron base in water;

b) acidifying the solution with hydrogen chloride to form a precipitate;

c) washing the precipitate; and

d) crystallizing pure ondansetron hydrochloride dihydrate from water and in the presence of activated carbon.

47. (Currently amended) A pharmaceutical formulation comprising ondansetron hydrochloride dihydrate, wherein the ondansetron hydrochloride dihydrate has a purity of at least about 99.9% and an exo-methylene content of less than ~~about~~ 0.01%, and wherein the ondansetron hydrochloride dihydrate is prepared by the process of:

a) preparing a solution of ondansetron base in water;

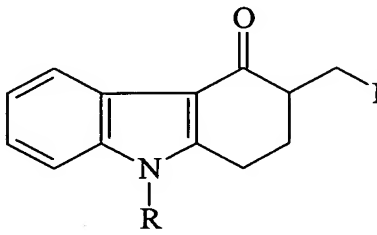
b) acidifying the solution with hydrogen chloride to form a precipitate;

c) washing the precipitate; and

d) crystallizing pure ondansetron hydrochloride dihydrate from water and in the presence of activated carbon.

48. (Previously presented) Ondansetron hydrochloride dihydrate as in claim 42, 43, or 44, wherein the ondansetron base is prepared by the process of:

a) preparing a solution of methyl-imidazole and dimethylamino-methyl-carbazolone of the formula



(where R = C_{1-4}, alkyl)

b) heating the solution;

c) removing a precipitate containing ondansetron base from the solution;

d) washing the precipitate;

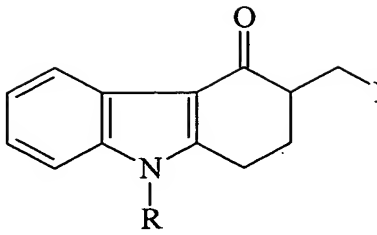
e) drying precipitate to obtain ondansetron base;

wherein the solution of methyl-imidazole and dimethylamino-methyl-carbazolone is prepared by adding about 4 to about 6 equivalents methyl-imidazole to one equivalent dimethylamino-methyl-carbazolone.

49. (Previously presented) Ondansetron hydrochloride dihydrate as in claim 42, 43, or 44, wherein the crystallization step is performed only once.

50. (Previously presented) The pharmaceutical formulation comprising ondansetron hydrochloride dihydrate as in claim 45, 46, or 47, wherein the ondansetron base is prepared by the process of:

a) preparing a solution of methyl-imidazole and dimethylamino-methyl-carbazolone of the formula



$N(Me)_2$. HCl (where R = C_{1-4}, alkyl)

b) heating the solution;

c) removing a precipitate containing ondansetron base from the solution;

d) washing the precipitate;

e) drying precipitate to obtain ondansetron base;

wherein the solution of methyl-imidazole and dimethylamino-methyl-carbazolone is prepared by adding about 4 to about 6 equivalents methyl-imidazole to one equivalent dimethylamino-methyl-carbazolone.

51. Cancelled.